

Docket No.: AB-122U

REMARKS/ARGUMENTS

By way of the present amendment, Claims 1-3, 6-9, 16 and 17 have been amended. Claims 10, 11, 14, 18 and 20 have been canceled. The claims have been amended to place them in condition for allowance or in better form for appeal. Fifteen (15) claims, Claims 1-9, 12-13, 15-17, 19 and 20, remain pending in the application. Entry of this amendment, and an indication of allowability with respect to the remaining claims is earnestly solicited. In the alternative, a prompt advisory action indicating the status of the present amendment (entered or not entered) would be most helpful.

By way of overview, the independent claims have all been amended to include, *inter alia*, the subject matter of prior dependent claims 2, 3 and 6, as well as subject matter from the canceled claims. As now amended, the independent claims all include, as elements of the deep brain stimulation system, an IPG (with at least one electrode array), a hand held programmer, a clinician's programmer, and a manufacturing and diagnostic system. Further, these independent claims all specify that the hand held programmer: (1) allows a patient to monitor and perform limited programming of the IPG; and (2) functions as a communication interface between the IPG and the clinician's programmer and manufacturing and diagnostic system, i.e., provides for separate communication links between it and the IPG, between it and the clinician programmer, and between it and the manufacturing and diagnostic system. Such a "simple but highly advanced hand held programmer control interface through which the patient may easily change stimulation parameters within acceptable limits" (see, e.g., abstract) is not shown or suggested in the prior art.

Claim Rejections – 35 U.S.C. §112

The independent claims have all been amended to remove the objectionable "only" therefrom, and Claim 1 has been amended to address the indefinite concerns raised by the Examiner.

Docket No.: AB-122U

Claim Rejections – 35 U.S.C §102/103

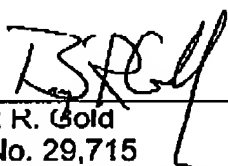
All of the independent claims, Claims 1, 9 and 17, have been amended by way of the present amendment to distinguish the claimed invention over Fischell, et al. (EP 0911061). More particularly, as presently amended, each of these independent claims require that the deep brain stimulation system include, in addition to an implantable pulse generator (IPG) having at least one electrode array, a hand held programmer, a clinician's programmer, and a manufacturing and diagnostic system, as shown in applicants' Fig. 1, and as described in connection with Fig. 1. As claimed, the hand held programmer (HHP): (1) allows a patient to monitor and perform limited programming of the IPG; and (2) functions as a type of external communication interface between the IPG and the clinician's programmer and manufacturing and diagnostic system, i.e., provides for separate communication links between the HHP and the IPG, between the HHP and the clinician programmer, and between the HHP and the manufacturing and diagnostic system. Such a "simple but highly advanced hand held programmer control interface through which the patient may easily change stimulation parameters within acceptable limits", cover page, abstract, lines 11-14, is not shown or suggested in the prior art. The closest teaching of Fischell, et al., to the use of a hand held programmer of the type claimed is the patient initiating device 750 (Fig. 18 and accompanying text), but such device only performs the function of allowing the patient, by pressing the button 752, to turn the implanted device ON or OFF. There are no teachings or suggestions that such patient initiating device 750 could be used to allow the patient to monitor and/or program the implanted device, or to serve as a communication interface with an external clinician's programmer or an external manufacturing diagnostic system, as claimed by applicant. Rather, Fischell et al. teach more conventional communication means, e.g., the use of a flat coil 637 embedded within a cap 636, which coil is attached to wires 638 which are connected to the external equipment 11. See Fig. 19 and accompanying text.

Docket No.: AB-122U

In view of the above, it is submitted that applicants' invention defines patentable subject matter. The issuance of a timely Notice of Allowance is therefore earnestly requested.

Respectfully Submitted,

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Date



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Page 10 of 10